REMARKS

The Office action mailed 10 February 2005, has been received and its contents carefully noted. The pending claims, claims 4, 11, 12, 22-25 and 29-31, were rejected. By this amendment, claims 4, 24 and 25 have been amended and claim 32 has been added. Claim 31 has been canceled as being a substantial duplicate of claim 4. Claim 4 has been amended to limit the microfluidized lysate preparation to those that do not cause false positive hypersensitivity reactions and to change the composition claim from a product-by-process to a straightforward composition claim. Claims 24 and 25 have been amended for consistency and shall not be construed as a limiting amendment as "composition" and the "microfluidized lysate preparation" as recited in the claims are the same. Hence the scope and meaning of claims 24 and 25 have not been modified by this amendment. Claim 32 has been added to cover subject matter deleted by the amendment to claim 4. Support may be found in the specification and the claims as originally filed. No statutory new matter has been added. Therefore, reconsideration and entry of the claims as amended is respectfully requested.

Rejection under 35 U.S.C. 102(b)

The Examiner rejected claims 4, 22, 24, 25, and 29-31 under 35 U.S.C. 102(b) as being anticipated by Leishmania Research Project DoD-8B or Stiteler et al. Specifically, the Examiner deemed that the claims are drawn to a product-by-process and as such the prior art anticipates the claimed invention since the Examiner deemed that how the product is prepared does not impart any patentable weight on the claimed product.

Applicants respectfully submit that the claims as amended are not product-by-process claims, but rather straightforward composition claims. In addition, the claims as amended, limit the microfluidized lysate preparations to those that do not cause a false positive hypersensitivity reaction. The prior art does not enable microfluidized lysate preparations that do not cause false positive hypersensitivity reactions. Specifically, the prior art does not teach or suggest which ingredients in the lysate preparations might be responsible for causing false positive hypersensitivity reactions. In order to be enabling, the prior art would have to teach or suggest that dextran was the ingredient that caused false positive hypersensitivity reactions. Nowhere do the cited prior art teach or suggest that dextran was the ingredient in the microfluidized lysate

preparations that caused false positive hypersensitivity reactions. Consequently, the cited prior art is nonenabling and as a result can not anticipate the claimed invention.

Therefore, Applicants respectfully assert that the claims as amended are novel and the rejection under 35 U.S.C. 102(b) should properly be withdrawn.

Rejection under 35 U.S.C. 103(a)

The Examiner rejected claims 4, 11, 12, 22-25, and 29-31 under 35 U.S.C. 103(a) as being unpatentable over Leishmania Research Project DoD-8B or Stiteler et al. and further in view of Reed et al. Specifically, the Examiner deemed that it would have been obvious to one of ordinary skill in the art to formulate the microfluidized lysate of DoD-8B or Stiteler et al. with phenol stabilizers of Reed et al. and to use such preparations in kits for diagnostic purposes.

Applicants respectfully submit that the microfluidized lysate preparations of the claimed invention are limited to those that do not cause false positive hypersensitivity reactions. As noted above, neither Leishmania Research Project DoD-8B nor Stiteler et al. teach or suggest which ingredients of the lysate preparations cause false positive hypersensitivity reactions. Thus, neither Leishmania Research Project DoD-8B nor Stiteler et al. teach or suggest a microfluidized lysate preparation that does not cause false positive hypersensitivity reactions when administered to subjects. Reed et al. do not alleviate the deficiencies of Leishmania Research Project DoD-8B or Stiteler et al. Reed et al. is directed to select peptides that are immunogenic. Nowhere do Reed et al. teach or suggest microfluidized lysate preparations that do not cause false positive hypersensitivity reactions. Nowhere do any of the cited prior art teach or suggest that in order to prevent false positive hypersensitivity reactions, the microfluidized lysate preparations must always be free of dextran all of the time. Thus, none of the prior art, alone or in combination, teach or suggest microfluidized lystate preparations which do not cause false positive hypersensitivity reactions as claimed.

Therefore, the prior art do not teach or suggest the invention as claimed and the rejection under 35 U.S.C. 103(a) should properly be withdrawn.

Request for Interview

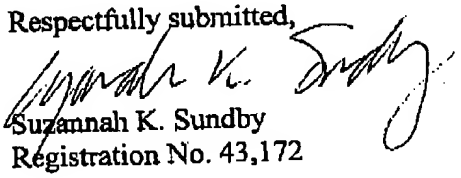
Applicants respectfully request either a telephonic or an in-person interview should there be any remaining issues.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. §1.136(a), and any fees required therefor are hereby authorized to be charged to **Deposit Account No. 210-380,** Attorney Docket No. **034047.013 (WRAIR 98-40/46).**

Respectfully submitted,



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I hereby certify that this correspondence is being:
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On 9 May 2005, by Suzannah K. Sundby

Signed: